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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,892

Applicant(s)

HIRAMOTO ET AL.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7-26-04 & 3-6-06
8-30-04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of election of species in the reply filed on February 7, 2006 is acknowledged. The traversal is on the ground(s) that AGA (US 2002/0068094) does not disclose sugars and the present application is "product of browning reaction." This is not found persuasive because as disclosed in [0032] of AGA, that proteins and saccharides are used in combination with food ingredients and would be heated which would cause a browning reaction of sugar and protein.

The requirement is still deemed proper and is therefore made FINAL.

Applicant noted to Examiner in a telephone call on February 7, 2006 that in the election/restriction dated January 12, 2006 that on page 3, line 5 that the term "different" should be --similar--. Examiner has noted it.

Claims Pending

Claims 1-21 are pending. Claims 1-21 will be examined on the merits solely in regard to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ameliorating diseases associated with *Helicobacter pylori*, does not reasonably provide enablement for preventing diseases associated with *Helicobacter pylori*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of

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working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claim is broadly drawn to preventing diseases associated with *Helicobacter pylori*. The specification is not considered to enable this use. "Prevention" of diseases associated with *Helicobacter pylori*, requires prevention of each and every instances of diseases associated with *Helicobacter pylori*. Such prevention is difficult, if not impossible, to achieve. Applicant's specification does not give any examples that show that the browning reaction of sugar and protein is able to prevent diseases associated with *Helicobacter pylori*. On page 19, lines 8-9 of specification, Applicant disclose that the treatment "significantly decreased the amount of *Helicobacter pylori*." Applicant does not discuss the known means for preventing diseases associated with *Helicobacter pylori*. Thus, Applicant does not provide enough information for a person of ordinary skill in the art to determine without undue experimentation that browning reaction of sugar and protein claimed are able to prevent diseases associated with *Helicobacter pylori*.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, the recitation "absorbance at 405 nm becomes at least 0.01 in a 5% aqueous solution" is unclear as to what Applicant is meaning because it is not known what is encompassed and it is not defined in the specification. What is the "0.01"? Clarification is needed.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim *et al.* (US 6,627,238).

Applicant's claims are drawn to product-by-process claims. The product is browning reaction of sugar and protein. Regarding product-by-process claims, note that MPEP § 2113 states that:

“[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate... A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).”

Kim *et al.* (US 6,627,238) teach the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) and can be used with an aqueous emulsion. Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 1, lines 24-30; column 2, lines 4-10). The reference does not specifically teach that the product is used as an adhesion inhibitor for *Helicobacter pylori* as claimed by Applicant in claim 1. However, the reference product reasonably appears to be the same product as claimed because the reference product is produced from the same sources as claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the

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claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidence by their shared browning reaction with sugar and protein activity.

Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Internet website "Science of Candy" (October 2002) (whole document).

Applicant's claims are drawn to product-by-process claims. The product is browning reaction of sugar and protein. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate... A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

"Science of Candy" (October 2002) teaches that a reaction between heating sugar and protein is well-known in making candy and is called *Maillard reaction* (whole document). The Internet website "Science of Candy" discloses that heating sugar and protein is well-known in making candy. The reference does not specifically teach that the product is used as an adhesion inhibitor for *Helicobacter pylori* as claimed by Applicant in claim 1. However, the reference product reasonably appears to be the same product as claimed because the reference product is produced from the same sources as claimed.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was

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made in view of the clearly close relationship between the extract as evidence by their shared browning reaction with sugar and protein activity.

Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim *et al.* (US 6,627,238) in view of Kodama (US 6,828,298).

Kim *et al.* (US 6,627,238) discloses the well-known Maillard reaction, which is combining naturally occurring sugars and proteins and heated (i.e. browning) and can be used with an aqueous emulsion. Kim discloses that lactose could be used as the sugar and casein, an animal protein derived from milk, as the protein. The browning composition of the sugar and protein is used in food products (column 1, lines 24-30; column 2, lines 4-10).

Kim does not disclose wherein the product is used as an adhesion inhibitor for *Helicobacter pylori* or wherein the food is raw cow's milk or milk powder or skim milk powder or whey or evaporated milk or wherein the browning reaction is carried out at an absorbance at 405 nm or wherein using the browning reaction of sugar and protein is used with an inhibitor of

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gastric-acid secretion or other substances capable of eradicating *Helicobacter pylori* such as a polyphenol or an antibiotic or an antibody against *Helicobacter pylori* or a polysaccharide or glycoprotein capable of binding to a *Helicobacter pylori* urease or wherein a pharmaceutical composition is used to treat diseases associated with *Helicobacter pylori* or wherein a method for inhibiting *Helicobacter pylori* by administering an effective amount of the product of the browning reaction between sugar and protein.

Kodama (US 6,828,298) discloses a glycoprotein capable of binding to *Helicobacter pylori* urease. Glycoproteins contained in bovine milk include lactoferrin (i.e. animal protein derived from milk). The glycoprotein is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori*. Kodama also discloses a food which treats diseases caused by or associated with *Helicobacter pylori* in mammals, including humans when consumed in an effective amount. Glycoprotein can be added to foods for special health use or special dietary use. Foods for specified health uses include milk and dairy products. Kodama also disclose that a pharmaceutical composition may further comprise an inhibitor of gastric acid secretion. The combination of glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* from the stomach. (column 2, lines 55-65; column 3, lines 1-11, 56-57; column 5, lines 27-67; column 6, lines 23-26, 66-67; column 7, 1-4).

One of ordinary skill in the art would have been motivated to use the product of the browning reaction between sugar and protein for inhibiting *Helicobacter pylori* adhesion inhibitor would be inherent to the food item. By adding the glycoprotein and gastric acid secretion inhibitor composition of Kodama with a food product, one would gain added benefits from the composition of Kodama. Although none of the references disclose the absorbance at 405 nm, one of skilled in the art would optimize that particular parameter. It was clear from Kim that the well-known Maillard reaction (i.e. the combining of naturally occurring sugars and proteins and heated (i.e. browning)) is routinely in food products. It was further clear from Kodama that a glycoprotein is capable of binding to *Helicobacter pylori* urease and is used as an inhibitor of *Helicobacter pylori* colonization in the stomach and is useful for treating diseases associated with *Helicobacter pylori* and be incorporated into a food product. Therefore, one of ordinary skill in the art would have had a reasonable expectation that by combining the browning

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reaction between sugar and protein and the glycoprotein and gastric acid secretion inhibitor composition with a food product, one would gain added benefits for *Helicobacter pylori* adhesion inhibitor.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

PATRICIA LEITH
PRIMARY EXAMINER

